DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 4, 2015

Nitiloop Ltd.
% Michael Daniel
President, Daniel & Daniel Consulting, LLC
Daniel & Daniel Consulting
340 Jones Lane
Gardnerville, Nevada 89460

Re: K143608
Trade/Device Name: NovaCross Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 10, 2015
Received: April 10, 2015

Dear Michael Daniel,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143608

Device Name

NovaCross Microcatheter, 1

Indications for Use *(Describe)*

The NovaCross Microcatheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature and for guidewire exchange.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional Premarket Notification Submission – 510(k)

NovaCross™ Microcatheter

510(k) Number K143608

I. SUBMITTER

Nitiloop Ltd.
8 Hamada St.
P.O.Box 12892
Herzliya, Israel 46733
Tel: +972-52-396-8925
Fax: +972-72-2501631

Contact Person

Michael A. Daniel
Daniel & Daniel Consulting, LLC
340 Jones Lane
Gardnerville, NV 89460
Tel: 775.392.2970
Cell: 415.407.0223
Fax: 610.545.0799
madaniel@clinregconsult.com

II. DEVICE

Name of Device: NovaCross™ Microcatheter
Common or Usual Name: NovaCross™ Microcatheter
Classification Name: Percutaneous catheter (21 CFR 870.1250)
Regulatory Class: II
Product Code: DQY

III. PREDICATE DEVICE

The primary predicate device is the Roxwood Medical, Inc. MultiCross Support Catheter cleared under K121763, (product code DQY, Regulation No. 870.1250).

A reference device was used in this submission:
Corsair Microcatheter (Asahi Intecc Co., Ltd. K083127).

IV. DEVICE DESCRIPTION

The NovaCross™ Microcatheter is a sterile, single-use, single lumen, over-the-wire, disposable percutaneous support catheter designed for use in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature for guidewire exchange.

The NovaCross™ Microcatheter consists of telescopic shaft, Over Tube, and a proximal Handle Body that allows for manual device manipulation and a means for flushing the catheter lumen. A key element of the device is a temporarily deployable and retractable distal Nitinol Scaffold, which is visible through fluoroscopy when deployed by the user, and expands to the width of the artery to provide an anchoring to aid the user in establishing greater support near the treatment site.

Subsequent to conventional guidewire placement, therapeutic devices such as atherectomy devices, PTCA catheters, and/or stents may be used to provide therapeutic benefit. The NovaCross™ Microcatheter by itself does not provide therapeutic benefit beyond simple facilitation of guidewire support. The NovaCross™ Microcatheter is similar in its design and it achieves its intended use by means of the same mechanisms as the predicate devices.

V. INDICATIONS FOR USE

The NovaCross™ Microcatheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the coronary and peripheral vasculature and for guidewire exchange.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the MultiCross, and the NovaCross™ Microcatheters have a working length of 135cm and are both compatible with a 7F guiding catheter, as well as a 0.014" guidewire. Like the MultiCross Nitinol scaffold, the NovaCross™ Nitinol scaffold is also expanded to the diameter of the artery when deployed.

The two devices use similar technology including a delivery system. The guidewire support with the two devices is accomplished by extending a Nitinol scaffold. The Nitinol element for the NovaCross™, like that of the MultiCross predicate, provides distal anchoring and support, thus exhibiting similar safety questions. These safety questions have been evaluated for the NovaCross™ Microcatheter through extensive design verification and validation testing, including a GLP Animal Study.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility testing
An evaluation of biocompatibility was performed in compliance with ISO 10993-1. Biocompatibility testing included cytotoxicity, irritation, acute systemic toxicity, sensitization, and hemocompatibility testing. All tests were successfully completed.

Sterilization, Packaging and Shelf Life Testing
Sterilization validation testing was performed to demonstrate compliance with ISO 11135-1. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

Mechanical Testing
Mechanical bench testing included the following:

- Dimensional
- Simulated use
- Tip flexibility
- Tip and shaft durability
- Torque response
- Torque strength
- Tensile strength
- Hydrophilic coating integrity
- Corrosion
- Fluid leak
- Air leakage
- Pushability and retractability
- Scaffold durability
- Radial force

All tests met the predefined acceptance criteria.

Animal Study
A GLP animal study, consisting of 6 pigs, was used to test whether the NovaCross™ device could be used safely and effectively as a tool to provide support to the guidewire. The system was used on three arteries (two coronary and one peripheral) in each animal. The safety of the system was evaluated 1 and 14 days post procedure in terms of the integrity of the treated vessels (compared to intact control segments), gross pathology and histopathology. The results demonstrated that no discernible pathological adverse effects were detected, in terms of local and systemic effects

following the deployment of the Test Item NovaCross™ Microcatheter in coronary and peripheral arteries. The Test Item successfully achieved all performance criteria defined in the study protocol. Pathology and histopathology analyses confirmed the results of the study.

VIII. CONCLUSIONS

The NovaCross™ Microcatheter was determined to be substantially equivalent to the predicate device.